

## **APPLICATION GUIDELINES**

**Release Date: October 19, 2007**

Department of Health and Human Services

National Institutes of Health

National Institute of Environmental Health Sciences

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### **Introduction**

The National Institute of Environmental Health Sciences (NIEHS) is proposing the continuation of a special Program of basic research grants directed towards understanding, assessing, and attenuating the adverse effects on human health resulting from exposure to hazardous substances. Grants made under the Superfund Hazardous Substances Basic Research Program [Superfund Basic Research Program] will be for coordinated, multi-component, interdisciplinary programs, and the objective is to establish and maintain a unique Program linking biomedical research with related engineering, hydrogeologic, and ecologic components.

These guidelines are to be used only in conjunction with the Request for Applications (RFA) ES-07-006, entitled "Superfund Basic Research and Training Program." The RFA details the scientific topics pertaining to this Program. A copy of the RFA is available from the NIH Guide for Grants and Contracts ([http://grants1.nih.gov/grants/guide/search\\_results.htm?year=active&scope=rfa](http://grants1.nih.gov/grants/guide/search_results.htm?year=active&scope=rfa)), the NIEHS website (<http://www.niehs.nih.gov/funding/grants/announcements/request.cfm>) or the Superfund Basic Research Program RFA Webpage, (<http://www.niehs.nih.gov/research/supported/sbrp/funding/rfa.cfm>)

Each funded grant is required to contain:

A minimum of:

Two (2) biomedical Research Projects (e.g., mechanistic based studies, epidemiology, human risk assessment, exposure assessment, genetic susceptibility, etc.) and;

Two (2) non-biomedical Research Projects (e.g., ecology, ecological risk assessment, fate and transport, hydrogeology, engineering, remediation, bioremediation, etc.)

An Administrative Core that includes:

- An external advisory committee

A Research Translation Core that includes:

- A plan for Partnership with Government Agencies
- A plan for Technology Transfer
- A plan for Communicating to Broad Audiences

One (1) Research Support Core. A Research Support Core must provide services to two or more Research Projects.

*If the requirements are not met, the application will be considered non-responsive and returned to the applicant.*

It is critical that the applicant recognize that the SBRP is more than just a basic research program and the applicant should make investments in other crucial areas of the Program. Therefore, in addition to the required elements, the SBRP strongly encourages the inclusion of:

- A Community Outreach Core
- A Training Core

The following restrictions apply to each application:

- A new applicant may request a budget for direct costs of up to \$2.1 million for the first year.
- Applicants submitting competing continuation grants may request up to a three percent increase above their last continuation project (non-competitive renewal) year's budget.

The budgets for each subsequent year may not exceed an escalation of three percent on recurring direct costs. Facilities and Administrative (F&A) costs incurred by requesting third party consortia or subcontracts are not included in the direct cost limitations, see NOT-OD-5-004. Applications that exceed the stated allowable budget caps for the first year will be returned non-responsive to the RFA.

- The total number of Research Projects and Research Support Cores cannot exceed 12. The Administrative, Research Translation, Community Outreach and Training Cores do not count towards this total.
- The Community Outreach Core is limited to \$100,000 direct costs in the first year, with subsequent years subject to the standard three percent cost escalations allowed by NIH. .
- The direct costs of the Training Core are not to exceed six percent of the total direct costs for the total program budget.

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## Application Procedures

### A. PHS 398 INSTRUCTIONS

Applications must be prepared using the most current PHS 398 research grant application instructions and forms (rev. 04/2006). The PHS 398 is available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: [grantsInfo@nih.gov](mailto:grantsInfo@nih.gov).

The RFA label available in the PHS 398 must be affixed to the bottom of the face page of the application. *Failure to use this label could result in delayed processing of your application such that it will not reach the review committee in time for review.*

As the PHS 398 is used primarily for the traditional research grant applications, several sections of the PHS 398 must be modified and expanded to provide the additional information needed for the reviewers to evaluate Superfund Basic Research Program applications. Detailed guidelines are presented below to assist the applicant in making the necessary modifications. It is important to note that these guidelines are intended as a supplement to the instructions in the PHS 398 and; therefore, the latter instructions will not be repeated extensively in this document. The structure provided in these instructions is not intended to preclude the consideration of deviations made on a case-by-case basis after discussions with and concurrence by appropriate institute staff.

## B. SUBMISSION INSTRUCTIONS

The signed original and three copies of the completed application, including the checklist, should be mailed to the Center for Scientific Review (CSR). Addressed labels are included in the PHS 398. **Do not include appendix material in copies sent to the CSR.**

Center for Scientific Review  
National Institutes of Health  
6701 Rockledge Drive  
Room 1040-MSC 7710  
Bethesda, MD 20892-7710  
(Courier and express services use zip code 20817)

At the time of submission to CSR, two additional signed copies of the application and five copies of collated appendix materials (Appendix material should be clearly identified and collated by project and core; do not staple or bind) must be sent to:

Linda Bass, Ph.D.  
Scientific Review Branch  
Division of Extramural Research and Training  
National Institute of Environmental Health Sciences  
PO Box 12233, EC-30  
79 T.W. Alexander Drive  
Research Triangle Park, North Carolina 27709  
Telephone: (919) 541-1307  
FAX: (919) 541-2503  
Email: [bass@niehs.nih.gov](mailto:bass@niehs.nih.gov)

*Note:* The appendix material should not be stapled or bound.

Applications must be received at CSR and NIEHS by **April 15, 2008**.

It is essential to note that the application submitted is the document of record. No substitutions of pages will be allowed. However, if the Principal Investigator wishes, he/she may submit errata documents to the NIEHS SRA.

There is a period of several months between the time of submission of the application and the initial review. In the event of substantial new findings during this interval, the applicant is encouraged to contact the SRA to seek permission to submit supplementary materials. These materials will generally not be accepted within 30 days prior to the initial scientific review. The SRA will make the final determination as to what additional information will be provided to the reviewers.

## C. DEFINITIONS

**Division of Extramural Research and Training (DERT)** – This is the component of the National Institute of Environmental Health Sciences that is responsible for the organization, funding and management of the extramural research and training grants programs.

**SBRP Program Administrator** – The NIEHS science administrator that is responsible for the development of initiatives and for the scientific management of the Superfund Basic Research Program. This person serves as the focal point for all science-related activities associated with the negotiation, award and administration of grants.

**Grants Management Specialist** – The NIEHS official that serves as the focal point for all business-related activities associated with the negotiation, award and administration of grants.

**Scientific Review Administrator (SRA)** – The NIEHS science administrator that is responsible for the organization, management and documentation of the initial review process for applications.

**Special Emphasis Panel (SEP)** – An ad hoc advisory group composed of primarily non-Federal scientific experts who conduct the scientific and technical merit review (initial review) of grant applications and assign priority scores to applications recommended for further consideration. The SEP is one type of IRG, or Initial Review Group, referred to in many NIH publications. SEPs will be convened to review the Superfund Basic Research Program applications.

**Summary Statement** – The official record of the evaluation and recommendations of the SEP.

**National Advisory Environmental Health Sciences (NAEHS) Council** – A chartered advisory committee, composed of both scientists and lay members, which performs the final advisory review of grant applications and advises on matters of significance to the policies, missions and goals of the NIEHS. The members include outstanding authorities knowledgeable in relevant programmatic areas that are especially concerned with the health needs of the American people.

**Superfund Basic Research and Training Program Grant (P42)**, commonly referred to as the Superfund Basic Research Program (SBRP) – An assistance grant award mechanism for the support of a broadly based multidisciplinary research program that has a well-defined central research focus on understanding, assessing or attenuating the human and ecological health effects of exposure to hazardous substances in the environment, and in developing novel approaches for identifying or remediating these contaminants as found in the environment. Interrelationships among component projects are expected to result in a greater contribution to the program goals than if each project were pursued separately. The "P42" designation is the NIH activity code that identifies a special program (comprised of multiple projects) application or grant.

**Principal Investigator (P.I.)** – The one person designated by, and responsible to, the applicant/awardee institution for the scientific and administrative direction and proper conduct of all aspects of a Superfund Basic Research Program grant.

**Project/Core Leader** – The investigator who is responsible for the scientific direction and conduct of an individual Research Project or Core component of a Superfund Basic Research Program grant.

#### **D. PRE-APPLICATION CONSULTATION WITH PROGRAM STAFF**

We encourage inquiries concerning this RFA and welcome the opportunity to answer questions from potential applicants. Because of the complexity of the Superfund Basic Research Program, applicants are strongly encouraged to contact SBRP program administrators early in the grant preparation process.

Communications between a potential Principal Investigator and the SBRP program administrators at the pre-application planning phase will serve to (1) advise the applicant concerning the areas of program interests of the NIEHS; (2) facilitate the receipt of a well organized, tightly focused application; and (3) ensure that the application conforms to established guidelines and criteria for a P42 application.

SBRP program administrators are particularly cognizant of the scope of the Superfund Basic Research Program and of the P42 guidelines, and are especially qualified to advise applicants concerning the preparation of a complete and well-developed application. Although the applicant is encouraged to seek guidance from program administrators before the receipt of applications, such guidance does not presume or guarantee an award. The initial contact with program administrators is the responsibility of the potential applicant. This interaction may take the form of correspondence, such as e-mail, telephone conversations, etc. Such communication will provide an opportunity to discuss issues such as the need for integration of all projects into the theme of the overall program, the established review guidelines, the proper format of the applications, and the necessary relevancy of the proposal to the programs supported by the NIEHS. However, program administrators will not provide a scientific critique of a draft application.

Prospective applicants are asked to submit a **letter of intent** that includes a descriptive title of the proposed application, the name, address, and telephone number of the Principal Investigator, and the number (i.e., ES 07-006) and title of the announcement (i.e., Superfund Basic Research and Training Program) to which the application is being submitted. NIEHS also requests that the letter include a descriptive title for each project and core, and the name of the project or core leader. Other key personnel and participating or collaborating institutions should also be included.

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows the scientific review administrator to estimate the potential review workload, determine the scientific expertise needed for the review panel, and helps avoid conflicts of interest in the review. The letter of intent should be sent to Dr. Linda Bass, the Scientific Review Administrator as listed under "B. Submission Instructions" of this document.

#### **E. GENERAL INSTRUCTIONS**

This section supplements the information and instructions found in the PHS 398. Except as modified in the following sections, the official instructions for the PHS 398 must be followed for all new and competitive renewal applications.

**Typeset Requirements.** The typeset limitations described for PHS 398 must be adhered to for all applications.

**Page Limitations.** The page limitations specified for PHS 398 apply to the individual projects and cores of the application. The component relating to the Program Plan (Section II of this document) should be as concise as possible. It is not appropriate for additional information, such as research description for individual projects, to be included in the overall program description.

**Page Numbering.** All pages should be numbered consecutively throughout the application beginning with the Face Page as page 1. Number the PHS 398 form pages as necessary. Individual Research Projects and Cores should become part of the overall numbering, and must not be numbered separately.

**Organization of the Application.** The components of the application should be in order as suggested in Illustration 1 at the end of this document. Following this format will facilitate the review of the application.

## F. SPECIFIC INSTRUCTIONS

### SECTION I

**The Face Page.** PHS 398 Form Page 1 (Face Page). The title for the application (# 1) should be chosen to correspond to the major theme of the program. Under #2, check "YES" in response to a specific Request for Application, use ES-07-006 for the Number and include "Superfund Basic Research and Training Program" for the Title. This information is essential for the expeditious assignment of the application. Affix the PHS 398, RFA label to the bottom of the page.

**Description, Performance Sites, and Key Personnel.** PHS 398 Form Page 2 (Page 2). Provide an abstract of the overall theme of the proposed multi-project program, the research strategy including the integration of a multidisciplinary research approach, the relevance to Superfund and the benefits to be achieved.

For Performance sites, indicate where the work described in the Research Plans will be conducted. If there is more than one performance site, list all the sites, including Veteran's Administration facilities and foreign sites, and provide an explanation on the Resources Format page of the application.

The Key Personnel should include the Principal Investigator and each of the Project and Core leaders and consultants (if considered Key Personnel). List the Principal Investigator's last name first. All other key personnel should be listed in alphabetical order, last name first. For each individual provide: name, organization (their institutional affiliation), and role on the project. Under role on the project, indicate how the individual will function with regard to the proposed project (e.g., Principal Investigator, Project Leader, Core Leader, etc.). Use additional pages as necessary.

**Complete Research Grants Table of Contents.** One complete Table of Contents, similar in format to the PHS 398 Form Page 3, must be provided and should follow the overall page numbering indicated above. Bearing in mind that the application will be reviewed project by project, prepare a detailed Table of Contents that will enable reviewers to find specific information readily. Projects/cores should be identified by number or letter, title, and name of the project/core leader.

**Detailed Composite Budget for First 12-month Period.** PHS 398 Form Page 4. Summarize the budget for the entire Program. (Follow the PHS 398: "Detailed Budget for Initial Budget Period.") Continuation pages may be used if needed to list all personnel.

**Composite Budget for All Years, All Projects.** PHS 398 Form Page 5 (Budget for Entire Proposed Period of Support). Summarize the budget for the entire Program for the requested additional years of support. Applicants may request a project period of up to five years.

**Individual Budgets.** Using duplicate copies of PHS 398 Form Pages 4 and 5, prepare a separate budget for each individual project, sub-contract and core unit. In the upper left hand corner, identify the project number or core. All proposed costs must be fully justified for both the initial 12-month and future year budgets as indicated in the PHS 398 instructions.

It is the intent of the NIEHS to hold annual meetings of grantees under this Program. Funds for travel by appropriate staff (i.e., Principal Investigator, Business Manager, and four students) to attend a three-day meeting should be included in the Administrative Core's budget for each year. The Community Outreach Core and Research Translation Core Leaders should also plan on attending the annual meeting. Expenses for this travel should be included in individual core budgets. The location of the meeting site will rotate among the different grantees.

Other budget considerations: the direct costs for the Training Core are not to exceed 6% of the total direct costs for the entire program budget; the Community Outreach Core is not to exceed \$100,000 direct costs in the first year with subsequent years subject to the standard cost escalation of three percent.

**Table of Research Support Core Utilization.** In order to assist the reviewers in determining the relationship between the Research Support Cores and the Research Projects, a table should be provided that indicates the percentage use of each core relative to the individual projects. See Illustration 2.

**Table of All Professional and non-Professional Personnel.** In order to aid in the review of the application, a tabular listing of all participating personnel should be prepared. List the Principal Investigator first followed by everyone else, in alphabetical order. This is to include everyone listed in the application. Information to be included in this table: name, role in program and associated project (i.e., Project Leader, senior investigator, post doctoral student, graduate student, technician, consultants, etc.) and affiliation (department or collaborating institution as appropriate). To be in compliance with NIH Conflict of Interest policy ([http://grants2.nih.gov/grants/peer/COI\\_Information.doc](http://grants2.nih.gov/grants/peer/COI_Information.doc)), you should include external advisory members **only** if they provided input in the design and preparation of the application. See Illustration 3.

**Biographical Sketches.** PHS 398 Biographical Sketch Format Page. Provide biographical sketches for all KEY investigators and Other Significant Contributors, including consultants. The Principal Investigator's biographical sketch should precede all others; others should follow in alphabetical order. Use duplicate copies of the Biographical Sketch Format page for each investigator. Include only one copy of each biosketch in the application. NOTE: Biographical Sketches may not exceed four pages. Items A and B (positions and honors, and selected peer-review publications and manuscripts in-press) may not exceed two of the four-page limit. Item C provides information on research support. List both selected ongoing and completed (during the last three years) research projects (federal or non-federal support). **Begin with the projects that are most relevant to the research proposed in this application.** Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Note: Do not include person months or direct costs.

**Table of Use of Human Subjects or Vertebrate Animals.** In order to facilitate the identification of projects and cores using human subjects and/or vertebrate animals, a table should be included. List all Research Projects and Cores indicating the information requested on the PHS 398 Face Page (AA) #4 and #5. See Illustration 4.

**Institutional Environment and Resources.** PHS 398 Resources Format Page. Include a brief description of the environment where the overall program and other activities will be conducted. If more than one campus or location will be involved, briefly describe each setting. If unique resources are available, briefly describe these and their relevance to the proposed program.

## SECTION II: PROGRAM PLAN

This section is unique to a multi-project application. The information requested in this section, for the most part, is not covered in the PHS 398.

**Program Introduction.** Provide an overall introduction and description to the program. Use greater detail than that presented in the "Description" on Form Page 2. Include the major theme of the program, goals and objectives, background information, relevance of the program to the Superfund Program, and the overall importance of the research. The introductory section should also include a description of the multidisciplinary and interdisciplinary nature of the program, how each project

and core contributes to the theme, and how the program will achieve the integration and the interaction of the biomedical and non-biomedical research.

**Principal Investigator.** A description of the role of the Principal Investigator should be included. Information on how s/he will coordinate, integrate and provide guidance to the program should be presented. Relevant experience may also be cited.

**Organizational Structure.** Describe the organizational structure of the program including an administrative and management plan that will achieve an integrated, coordinated multi- and inter-disciplinary research program. A diagram may be useful in demonstrating the interactions between the different program units. In broad terms, describe how the Administrative Core supports the overall goals and organization of the program. Describe the roles of the advisory board. Also, describe the relationships between the proposed Superfund Basic Research Program within the academic institution, and its interactions with other centers, institutes, departments and central administration.

**Additional Instructions for Renewal Applications.** Competing renewal applications must include a general progress report that describes achievements under the grant since the last competitive review. The Principal Investigator should carefully prepare this section, and it should not be a copy of the material included for the individual projects. (The individual research projects will also provide individual progress reports as requested in the PHS 398 instructions.) This is the section where the benefits of the program can be expressed/demonstrated. Items to be included are:

- A brief summary of major accomplishments that can be attributed to the Superfund Basic Research Program Grant, and a brief explanation of how they have contributed to the goals of the grant and the national Superfund Program.
- Detailed reports on projects and cores that are not being continued, and the reason for deleting them from the program.
- A table listing projects and core components (by project title and investigator) that denotes which projects have been discontinued or completed in the latest funding cycle. See Illustration 5.
- A table listing projects that are continuing, new, or substantially modified. This table should coincide in order and number with the projects and cores in the current application. Also indicate which projects are considered to be biomedical research and which are considered non-biomedical research. See Illustration 6.
- A list of all publications and completed manuscripts that are a direct result of the support provided by the Superfund Basic Research Program Grant. With an asterisk, denote each publication that is a result of formal collaborations among different projects within the program.

**Additional Instructions for Resubmission (amended) Applications.** All resubmission applications must include an "Introduction to Resubmission Application", **not to exceed three pages**. This introduction should discuss in general terms the overall concerns raised from the previous application and provide an overview of changes made. More detailed information should be provided at the beginning of each project and core. This information is **not to exceed three pages**. For these sections, list each area of concern noted in the Summary Statement for the previous project or core, and provide a detailed response to each concern. Summarize clearly the changes that have been made in the resubmitted (revised) project/core. Do not include an extensive description of each change in the introduction. In the body of the project /core, highlight paragraphs with significant changes by bracketing, indenting, or changing the typography. If the changes are so extensive as to include most of the text, this exception should be explained in the Introduction to the Resubmission Application. Do not underline or shade changes.

## SECTIONS III - VIII

### All Projects and Cores.



- For the title page of individual projects/cores use the PHS 398 Continuation Page and clearly denote the project/core number, the title of the project/core, and the project/core leader.
- The "Description" of the project/core should be prepared on a duplicate copy of PHS 398 Form Page 2. All performance sites and key personnel on the project/core should be identified.
- The name of the Principal Investigator of the P42 grant application is placed in the upper right corner of each page, not the name of the project/core leader. Also note: individual projects and cores must not exceed the 25-page limitation for items a - d of the Research Plan (follow PHS 398 instructions).
- Subsequent pages (following the Description, Performance, and Key Personnel, Form Page 2) should use Continuation Pages and follow PHS 398 Instructions. If collaborative or consortium arrangements are included in the application, follow PHS 398 Instructions. Discussion should be included as to how the collaborative arrangements will be of value in achieving the specific objectives of the project.
- The following information should not be included in the individual projects or cores. They should be included only in Section I of the application.  
 "Face Page" (Form Page 1)  
 "Research Grants Table of Contents" (Form Page 3)  
 "Detailed Budget for Initial Cost Period" (Form Page 4)  
 "Budget for Entire Proposed Period of Support" (Form Page 5)  
 "Biographical Sketch Format Page"
- Include "Letters of Commitment" and collaborative arrangements/consultants (Research Plan item "h") that are identified in the application.
- Include "Resources Format Page" within the individual Research Projects and Core sections. Include at the end of the Research Plan (a-i).
- Applicants should carefully read and adhere to the PHS 398 instructions concerning children, gender and minority inclusion in human study populations.
- Appendix material is not a part of the application and should not be used to circumvent the page limitations of the "Research Plan". See PHS 398 Instructions for list of appropriate Appendix Material. Please submit five collated copies of appendix material to Dr. Janice Allen, SRA, as listed in "B. Submission Instructions" of these guidelines. Appendix materials should be collated by Research Project and Core, and presented in the same order that they appear in the application. Do not staple or bind Appendix materials. The Appendix material should follow all copies of the application.

### SECTION III

**Research Projects.** Follow the instructions in the PHS 398 for the Research Plan (a - i) for describing the project. In addition, each individual project should clearly state its relevance to the overall program and its primary theme, its contribution to and its interactions with the other projects and the extent of its dependence on the cores. Research Projects should be designated as Project 1, Project 2, etc.

### SECTION IV

**Administrative Core.** Follow instructions in the PHS 398 (a - i) for the Research Plan as is appropriate for describing the Administrative Core. A narrative description should be provided that includes the planning and coordination of research activities; the integration of cross-disciplinary research; and the oversight of fiscal and resource management. Indicate who will be responsible for each of these activities. Describe the role(s) of advisory groups and consultants. If this is a competing renewal, summarize activities carried out during the preceding performance period.

### SECTION V

**Research Translation Core.** Follow instructions in the PHS 398 (a-i) for the Research Plan as is appropriate for describing the Research Translation Core. A narrative description should be provided that includes plans for (1) partnering with government agencies; (2) technology transfer; and (3) communicating with broad



audiences. In addition, a plan for the maintenance of ongoing communication with NIEHS should be included. Discuss how the Research Translation Core will interact with the other research projects and cores in fulfilling the goals of this core. Indicate who will be responsible for each of these activities

## SECTION VI

**Research Support Cores.** Follow the instructions in PHS 398 “Research Plan” (a - i) as is appropriate for describing the Research Support Core. Information that should be included is as follows:

- Describe the function of the core as a resource to the program. This section must clearly present the facilities, techniques, and professional skills that the core will provide. As justification for the core, briefly indicate the specific Research Projects that will use the resources of the core. A Research Support Core is principally designed as a service or resource component; it would be highly unusual to include research in a core (a possible exception would be methodology development). Please contact the Institute staff if you require guidance on this issue.
- Describe the role of the core as a resource to the program as a whole. Discuss ways in which these centralized services will produce an economy of effort and/or savings in overall costs compared to their inclusion as part of each project in the program.
- Applicants are advised that a Quality Assurance Statement must be included ONLY for Research Support Cores that provide analytical, quantitative services to the applicant’s program. If required, the Quality Assurance Statement should be included after “Research plan (a-i). Refer to “Section IV.6 – Other Submission Requirements” of the RFA for additional information.
- If this is a competing renewal, summarize activities carried out during the preceding performance period. Include core utilization by the individual Research Projects.

## SECTION VII (optional)

**Community Outreach Core.** Follow the instructions in PHS 398 “Research Plan” (a - i) as is appropriate for describing the Community Outreach Core. A narrative description should be provided that describes how the goals of the Community Outreach Core relate to the programmatic theme of the application, and how the Core Leader will interact with the Project Leaders. Indicate how this Core will coordinate with established community outreach groups. Note that this is a distinct core that is separate from the information transfer requirements of the Research Translation Core. Select a title that uniquely describes the activities of the Core. For competitive renewals, summarize the accomplishments and milestones met during the preceding performance period.

## SECTION VIII (optional)

**Training Core.** Follow instructions in the PHS 398 “Research Plan” (a - i) as is appropriate for describing the Training Core. A narrative description should be provided that reflects interdisciplinary approaches to training. For competitive renewals, it is important that the application identify the students who participated in the Training Core during the previous funding cycle.

## SECTION IX

**Plan for Sharing Data.** A data-sharing plan should be developed for the overall program, if appropriate. If the applicant deems that a data-sharing plan should not be included, a strong justification for its exclusion must be provided. For those including a data-sharing plan, the precise content will vary depending on the data being collected and how the investigator(s) is planning to share the data. For example, applicants may briefly describe the expected schedule for data sharing, the format of the final dataset, the documentation to be provided, whether or not any analytic tools also will be provided, whether or not a data-sharing agreement will be required and, if so, a brief description of such an agreement (including the criteria for deciding who can receive the data and whether or not any conditions will be placed on their use), and the mode of data sharing (e.g., under their own auspices by mailing a disk or

posting data on their institutional or personal website, through a data archive or enclave). Investigators choosing to share under their own auspices may wish to enter into a data-sharing agreement. For NIH instructions and policy see [http://grants.nih.gov/grants/policy/data\\_sharing/index.htm](http://grants.nih.gov/grants/policy/data_sharing/index.htm).

## SECTION X

**Checklist.** Fill out the PHS 398 Checklist Form Page; refer to the PHS 398 for further instructions.

## SECTION XI

**Appendix.** See the PHS 398 instructions for information on submitting appendix materials and refer to "B. Submission Instruction" of this document for number of copies and mailing instructions.

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### Review Procedures and Factors

For a description of the review procedures and review factors refer to RFA ES-07-006 "Superfund Basic Research and Training Program". When RFA ES-07-006 is issued, the applicant can obtain a copy from the NIH Guide for Grants and Contracts ([http://grants1.nih.gov/grants/guide/search\\_results.htm?year=active&scope=rfa](http://grants1.nih.gov/grants/guide/search_results.htm?year=active&scope=rfa)), the NIEHS website (<http://www.niehs.nih.gov/funding/grants/announcements/request.cfm>) or the Superfund Basic Research Program RFA Webpage (<http://www.niehs.nih.gov/research/supported/sbrp/funding/rfa.cfm>).

Detailed review criteria that will be used for assessing the overall merit of the multi-project grant proposal, the scientific merit of the individual research projects and cores, the multidisciplinary and interdisciplinary nature of the program and the qualifications of the Principal Investigator can be found in Section V.2 of the RFA. Additional review criteria and review considerations can be found in Sections V.2.A, V.2.B, V.2.C and V.2.D.

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### Policies and Assurances

The award and administration of Superfund Basic Research Program Grants are subject to the same policies and procedures as other research grants. These policies and cost principles are set forth in the current PHS Grants Policy Statement, other NIH and NIEHS issuances, and Federal legislation and regulations.

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### Staff Consultation

Prior to application submission and especially while the application is being developed, inquiries about the Superfund Basic Research Program application process may be addressed to any of the scientific program officials listed below:

Claudia Thompson, Ph.D.  
Center for Risk and Integrated Sciences  
Division of Extramural Research and Training  
National Institute of Environmental Health Sciences  
P.O. Box 12233, EC-27  
79 T.W. Alexander Drive  
Research Triangle Park, North Carolina 27709  
Phone: (919) 541-4638  
Fax: (919) 541-4937  
Email: [thomps14@niehs.nih.gov](mailto:thomps14@niehs.nih.gov)

Beth Anderson, M.A.  
Center for Risk and Integrated Sciences  
Division of Extramural Research and Training  
National Institute of Environmental Health Sciences  
P.O. Box 12233, EC-27  
79 T.W. Alexander Drive  
Research Triangle Park, North Carolina 27709

Phone: (919) 541-4481  
Fax: (919) 541-4937  
Email: [tainer@niehs.nih.gov](mailto:tainer@niehs.nih.gov)

Heather Henry, Ph.D.  
Center for Risk and Integrated Sciences  
Division of Extramural Research and Training  
National Institute of Environmental Health Sciences  
P.O. Box 12233, EC-27  
79 T.W. Alexander Drive  
Research Triangle Park, North Carolina 27709  
Phone: (919) 541-5330  
Fax: (919) 541-4937  
Email: [henryh@niehs.nih.gov](mailto:henryh@niehs.nih.gov)

Questions of an administrative or fiscal nature not directly related to the scientific aspects of the application should be directed to the Grants Management Branch officials listed below:

Susan Ricci  
Grants Management Branch  
Division of Extramural Research and Training  
National Institute of Environmental Health Sciences  
P.O. Box 12233, EC-30  
79 T. W. Alexander Drive  
Research Triangle Park, North Carolina 27709  
Telephone: 919-316-4666  
Fax: 919-541-2860  
[ricci@niehs.nih.gov](mailto:ricci@niehs.nih.gov)

Lisa Archer  
Grants Management Branch  
Division of Extramural Research and Training  
National Institute of Environmental Health Sciences  
P.O. Box 12233, EC-30  
79 T.W. Alexander Drive  
Research Triangle Park, North Carolina 27709  
Telephone: 919-541-0751  
Fax: 919-541-2860  
[archer@niehs.nih.gov](mailto:archer@niehs.nih.gov)

Once the application has been submitted to the NIH/NIEHS, the primary point of contact should be through the Scientific Review Branch officials listed below:

Linda Bass, Ph.D.  
Scientific Review Branch  
Division of Extramural Research and Training  
National Institute of Environmental Health Sciences  
P.O. Box 12233, EC-30  
79 T.W. Alexander Drive  
Research Triangle Park, North Carolina 27709  
Telephone: 919-541-1307  
Fax: 919-541-2503  
E-mail: [bass@niehs.nih.gov](mailto:bass@niehs.nih.gov)

Leroy Worth, Ph.D.  
Scientific Review Branch  
Division of Extramural Research and Training  
National Institute of Environmental Health Sciences  
P.O. Box 12233, EC-30  
79 T.W. Alexander Drive  
Research Triangle Park, North Carolina 27709  
Telephone: (919) 541-0670  
Fax: (919) 541-2503  
Email: [worth@niehs.nih.gov](mailto:worth@niehs.nih.gov)

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**Illustration 1: Outline for the Organization of the Application**

For ease of review it is strongly suggested that applications be organized according to the following outline:

## **SECTION I**

- Face Page
- Description, Performance Sites and Key Personnel
- Complete Table of Contents
- Detailed Composite Budget for First 12-month Period
- Composite Budget for All Years, All Projects
- Individual Budgets (Identify for each project/core individually)
- Table of Research Support Core Utilization
- Table of All Professional and Non-Professional Personnel
- All Biographical Sketches
- Table of Use of Human Subjects and Vertebrate Animals
- Institutional Environment and Resources

## **SECTION II: PROGRAM PLAN**

- Program Introduction:
  - a. Overall Theme
  - b. Goals and Objectives
  - c. Background Information
  - d. Relevance to the Superfund Program
  - e. Significance of the Research
  - f. Multidisciplinary and Interdisciplinary Approach
- Principal Investigator
- Organizational Structure
- Additional Information for Renewal Applicants
  - a. Major accomplishments
  - b. Reports on discontinued projects
  - c. Table of Discontinued or Completed Projects and Cores
  - d. Table of Continuing, New or Substantially Modified Projects or Cores
  - e. List of all publications

## **SECTION III: RESEARCH PROJECTS**

- Title Page: Include Title, Research Project Leader and Research Project number (1,2,3,etc.)
- Project Description, performance sites and key personnel (Form Page 2).
- Relation of Project to Overall Program
- Research Plan (a-d: 25 page limit)
  - a. Specific Aims
  - b. Background and Significance
  - c. Preliminary Studies/Progress Report
  - d. Experimental Design and Methods
- Human Subjects (e)
- Vertebrate Animals (f)
- Literature Cited (g)
- Consultants/Collaborative Arrangements w/ Letters of Commitment (if applicable) (h)
- Consortium/Contractual Arrangements (if applicable) (i)
- Resources (Resource Format Page)

***REPEAT THE ABOVE FOR EACH RESEARCH PROJECT***

#### **SECTION IV: ADMINISTRATIVE CORE**

- Title Page: Include 'Administrative Core' and Principal Investigator
- Project Description, performance sites and key personnel (Form Page 2)
- Relation of Core to Overall Program
- Administrative Plan (a-d: 25 page limit)
  - a. Specific Aims
  - b. Background and Significance
  - c. Preliminary Studies/Progress Report
  - d. Design and Approaches
- Consultants/Collaborative Arrangements w/ Letters of Commitment (if applicable) (h)
- Consortium/Contractual Arrangements (if applicable) (i)
- Resources (Resource Format Page) (if applicable)

#### **SECTION V: RESEARCH TRANSLATION CORE**

- Title Page: Include 'Research Translation Core' and Principal Investigator
- Project Description, performance sites and key personnel (Form Page 2)
- Relation of Core to Overall Program
- Research Translation Core Plan (a-d: 25 page limit)
  - a. Specific Aims
  - b. Background and Significance
  - c. Preliminary Studies/Progress Report
  - d. Design and Approaches
- Literature Cited (g)
- Consultants/Collaborative Arrangements w/ Letters of Commitment (if applicable) (h)
- Consortium/Contractual Arrangements (if applicable) (i)
- Resources (Resource Format Page) (if applicable)

#### **SECTION VI: RESEARCH SUPPORT CORES**

- Title Page: Identify Title, Research Core Leader and letter of Core (A,B,C, etc.)
- Project Description, performance sites and key personnel (Form Page 2)
- Relation of Core to Overall Program
- Research Support Core Plan (a-d: 25 page limit)
  - a. Specific Aims
  - b. Background and Significance
  - c. Preliminary Studies/Progress Report
  - d. Experimental Design and Methods
- Human Subjects (e)
- Vertebrate Animals (f)
- Literature Cited (g)
- Consultants/Collaborative Arrangements w/ Letters of Commitment (if applicable) (h)
- Consortium/Contractual Arrangements (if applicable) (i)
- Quality Assurance Statement (required for analytical/quantitative activities)
- Resources (Resource Format Page)

***REPEAT THE ABOVE FOR EACH CORE***

#### **SECTION VII: COMMUNITY OUTREACH CORE - (OPTIONAL)**

- Title Page: Identify by Title and Core Leader
- Project Description, performance sites and key personnel (Form Page 2)
- Relation of Core to Overall Program

- Community Outreach Core Plan (a-d: 25 page limit)
  - a. Specific Aims
  - b. Background and Significance
  - c. Preliminary Studies/Progress Report
  - d. Design and Approaches
- Literature Cited (g)
- Consultants/Collaborative Arrangements w/ Letters of Commitment (if applicable) (h)
- Consortium/Contractual Arrangements (if applicable) (i)
- Resources (Resource Format Page)

#### **SECTION VIII: TRAINING CORE - (OPTIONAL)**

- Title Page: List Title and Core Leader
- Project Description, performance sites and key personnel (Form Page 2)
- Relation of Project to Overall Program
- Training Core Plan ((a-d: 25 page limit)
  - a. Specific Aims
  - b. Background and Significance
  - c. Preliminary Studies/Progress Report
  - d. Design and Approaches
- Consultants/Collaborative Arrangements w/ Letters of Commitment (if applicable) (h)
- Consortium/Contractual Arrangements (if applicable) (i)
- Resources (Resource Format Page)

#### **SECTION IX: PLAN FOR SHARING DATA**

#### **SECTION X: CHECKLIST**

#### **SECTION XI: APPENDIX**

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**Illustration 2: Table of Research Support Core Utilization**

Research Projects	Research Support Core A	Research Support Core B	Research Support Core C
Research Project 1	50%	0	80%
Research Project 2	0	0	0
Research Project 3	50%	30%	20%
Research Project 4	0	70%	0

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**Illustration 3: Table of All Professional and Non-Professional Personnel**

Name	Role in Program	Affiliations
Dr. Georgia Matisse	Principal Investigator and Project Leader, Project 1	Dept. of Genetics, Univ of Moma
Ms. Helen Cassatt	Senior Technician, Project 1	Dept. of Genetics, Univ of Moma
Dr. Peter Catlett	Consultant	Dow Chemical Co.

Dr. Alfred Degas	Investigator, Project 3	Internat'l Institute of Genetics
Mr. Edgar Frankenthaler	Graduate Student, Project 4	Dept. of Engineering, Univ of Moma
Dr. Mary O'Keefe	Post Doc Fellow, Project 1	Dept. of Genetics, Univ of Moma
Dr. Henri Stieglitz	Core Leader, Core C and Investigator, Project 4	Dept. of Mol Bio, Univ of Moma

**Illustration 4: Table of Use of Human Subjects or Vertebrate Animals**

Project Number or Core Letter	Human Subjects	Vertebrate Animals
Project 1	No	No
Project 2	Yes	No
Project 3	No	Yes
Project 4	Yes	Yes
Core C	Yes	No

**Illustration 5: Table of Discontinued or Completed Projects and Cores**

Discontinued Project Number or Core Letter	Title of Discontinued Project or Core	Project or Core Leader
Project 2	Detection of PAHs in Humans	Jackson Gris
Project 5	Remediation of PAHs	Juan Monet
Core E	Outreach and Education	Claude Kolliwiz

**Illustration 6: Table of Continuing, New or Substantially Modified Projects or Cores**

Project Number/Core Letter	C/N/S*	Project Core Leader	Title	Previous Project Number/Core Letter	Biomedical or non-Biomedical**
Project 1	C	Georgia Matisse	Markers of Exposures to Mixtures	Project 1	Biomed
Project 2	C	Pablo Braque	Individual Susceptibility to Disease Risk	Project 3	Biomed
Project 3	S	Claude Pollock	Molecular Effects of Low Level Exposures	Project 4	Biomed
Project 4	N	Juan Monet	Redistribution of PAHs in Sediments	-	Non-Biomed
Core A	C	Georgia Matisse	Admin Core	Core A	-
Core B	N	Juan Monet	Tech Trans Core	-	-
Core C	C	Henri Stieglitz	Analytical Core	Core C	-



Core D	C	Kathe Pollack	Biomarker Core	Core B	-
Core E	N	Claude Kolliwitz	Supporting Community Involvement	-	-
Core F	C	Georges Picasso	Training Core	Core D	-

\* Continuing, New or Substantially modified.

\*\* For research projects only